

### Remarks

Claims 1, 4, 11, 13, 17, 21, 23, and 28 have been amended. Claims 10 and 30 have been cancelled. Claims 1, 3-5, 9, 11-13, 15, 17, 21-23, 28, and 31 remain in the application. Reconsideration and allowance of these claims as now presented is respectfully requested.

### Claim Objections

Claim 30 stand objected to under 37 CFR \$1.75(c) as being in improper form for being a multiple dependent claim depending from another multiple dependent claim. Claim 30 has been cancelled in the present amendment. Accordingly, the claim objection under 37 CFR \$1.75(c) should be withdrawn.

### Rejection of Claims Under 35 U.S.C. §112

Claim 4 stands rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification. Applicant respectfully submits that the Crodo Raw Materials listing of products, along with their associated INCI nomenclature, identifies Procetyl AWS, as identified on page 12, lines 5-12 of the application as originally filed, as being a synonym for PPG-5 Ceteth-20, the INCI nomenclature for such material. The Crodo Raw Materials listing was enclosed with the Amendment Under Rule 1.116, filed September 18, 2002. Therefore, PPG-5

Ceteth-20 was indeed disclosed in the specification as originally filed. To more particularly claim the invention, however, Claim 4 has been amended.

Claims 1, 3-5, 9-13, 15, 17, 21-23, 29 and 31 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 1, 13, 17, 21, 23, and 28 have been amended as requested by the Examiner to more particularly point out and distinctly claim the invention. With regard to the term "balanced" in Claim 3, the Examiner asserts that it is a relative term which renders the claim indefinite. This very issue was addressed by the Applicant in the amendment filed April 24, 2002, wherein the support for the definiteness of the term "balanced" was provided in Martindale The Complete Drug Reference, 32<sup>nd</sup> Ed, page 1468, and at page 8, lines 20-27 of the specification as originally filed. The above-noted passage in the specification defines the term "balanced" as when the isoelectric point of the molecule occurs at pH7. Therefore, Applicant submits that the term "balanced", as used in Claim 3, is sufficiently defined so as to be understood by one of ordinary skill in the art. The claim rejections under 35 U.S.C. §112 should accordingly be withdrawn.

### Rejection of Claims Under 35 U.S.C. §103

Claims 1, 3, 4, 5, 10, 11, 12, 17, 23, and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. (GB 2,202,145) in view of Jacobs et al. (U.S. 5,939,085) and Sang et al. (U.S. 6,143,310). Totten et al. '145 generally disclose dermatological compositions having nedocromil sodium and ethoxylated mixtures of cetyl and stearyl alcohols. The Jacobs et al. '085 patent is generally directed to skin smoothing compositions. The Examiner cites Jacobs et al. '085 for its identification of disodium cocoamphodiacetate as an emulsion-stabilizing surfactant. Sang et al. '310 disclose a cosmetic composition, and identify PPG-5 Ceteth-20 as a suitable solubilizing agent.

The primary essence of the present invention is the combination of an alkoxyated cetyl alcohol and an amphoteric surfactant in a pharmaceutical composition having a polar drug, which combination provides an unexpectedly enhanced dermatological transmission of the polar drug. Nowhere do the cited references, whether taken alone or in combination, teach or suggest the combination of an alkoxyated cetyl alcohol and an amphoteric surfactant providing such an enhanced dermatological transmission vehicle for a polar drug.

The Examiner cites Jacobs et al. '085 for its disclosure of disodium cocoamphodiacetate, and states a conclusion that it would have been obvious to produce the compositions of the present invention from the combined disclosures of Totten et al. '145, Jacobs et al. '085, and Sang et al. '310. There is simply no basis for the Examiner's conclusion of the obviousness of the compositions of the present invention. Applicant has diligently reviewed the cited prior art, and has found no teaching or incentive whatsoever to combine the surfactant of Jacobs et al. '085 with the dermatological composition of Totten et al. '145 to thereby obtain enhanced dermatological transmission of a polar drug as is presently claimed. Nowhere do the cited references teach or suggest enhanced dermatological transmission of a polar drug through the combination of an alkoxylated cetyl alcohol and an amphoteric surfactant.

The Examiner has repeatedly cited references that disclose individual components of the composition of the present invention. However, the Examiner has consistently failed to address the fact that the cited references do not teach or suggest combining such components so as to obtain the medical advantages discovered in the present invention. As such, the Examiner has failed to point out any incentive

in the cited references to combine the particular components in the manner prescribed by the present invention so as to effect enhanced transdermal transmission of a polar drug in a patient.

The unexpected nature of the presently claimed combination is demonstrated by the long felt need in the art for the development of an acceptable topical vehicle that allows adequate skin transmission of a polar drug, and particularly sodium cromoglycate and nedocromil sodium (see page 3, line 28-page 4, line 3 of the present application). In addition, the unexpected benefits of the claimed combination that are not taught or suggested in the cited prior art are specifically identified in the Declarations of Alan M. Edwards and Martin K. Church, which are enclosed herewith. The Declarations identify the unique advantages of the presently claimed invention, and particularly that the claimed composition is critical in the ability of the polar drug to be effectively absorbed by the skin for direct and enhanced treatment of skin maladies. Moreover, such Declarations specifically refer to the presently cited references in attesting that the benefits achieved through the claimed compositions are wholly unexpected in view of the teachings of the cited prior art. Finally, the Declaration of Alan M. Edwards identifies skin disease

treatment efficacy of the present invention that has not been demonstrated by any topical compositions of the prior art. In addition to the Declarations, a Curriculum Vitae for each Declarant has been enclosed herewith.

For the foregoing reasons, the claim rejections under 35 U.S.C. §103(a) should accordingly be withdrawn.

Claim 9 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085 and Sang et al. '310, and further in view of Dener et al. (WO 98/04537) and Haider (1979). The references of Dener et al. '537 and Haider, whether taken alone or in combination, fail to cure to the defects of the cited references discussed above. Therefore, the claim rejections based thereon should accordingly be withdrawn.

Claims 15 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085. The combination of Totten et al. '145 and Jacobs et al. '085, as discussed above, fail to teach or suggest the claimed compositions of the present invention. Accordingly, the claim rejections based thereon should be withdrawn.

Claim 31 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085, and further in view of Sang et al.

'310. For the reasons stated above, the cited references fail to teach or suggest the claimed combinations of the present invention for effecting enhanced dermatological transmission of a polar drug. Thus, the claim rejections based thereon should accordingly be withdrawn.

Claim 22 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085, and further in view of Dener et al. '537 and Haider. For the reasons stated above, the cited references, whether taken alone or in combination, fail to teach or suggest the compositions of the claimed invention. Accordingly, the claim rejections based thereon should be withdrawn.

For the foregoing reasons, the claims as presently amended are believed to be unobvious and patentable over the cited prior art, whether taken alone or in combination. Applicant therefore submits that the claims as currently presented are allowable on the merits. An early allowance is respectfully solicited.

Respectfully submitted,

HAUGEN LAW FIRM PLLP

A handwritten signature in black ink, appearing to read 'Mark J. Burns', written over the printed name.

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